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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,502	07/03/2003	Richard M. Beane	07917-160001 / UMMC 02-09	4420
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EXAMINER BLATT, ERIC D				
ART UNIT 3734		PAPER NUMBER		
NOTIFICATION DATE 07/22/2009		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/613,502

Applicant(s)

BEANE ET AL.

Examiner

Eric Blatt

Art Unit

3734

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 15-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 April 2009 has been entered.

Election/Restrictions

Claims 15-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 11, 2008.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poloyko et al. (US 5,741,276) in view of Poncet et al. (US 5,254,130).

Regarding claims 1, 2, and 6-8 Poloyko discloses a surgical suture placement device (Figures 2 and 3) comprising a handle assembly comprising a plunger 62, a suturing assembly having a needle 52, and a hollow inner tube 36 running between the handle assembly and the suturing assembly wherein the hollow inner tube 36, handle assembly, and suturing assembly are non-rotatably connected to one another. Polyoko fails to disclose an elongated hollow outer tube provided over the hollow inner tube 36 wherein the outer tube is rotatable relative to the handle assembly, inner tube 36, and suturing assembly. Poncet discloses a related minimally invasive device (Figure 2) wherein a distal tool 11 is non-rotatably coupled to an inner member 19, and an outer member 17 is provided over the inner member 19 wherein the outer member 17 is rotatable relative to the tool 11 and inner member 19. This construction allows the tool to be rotated about its axis from the handle of the device without rotating the tissue-contacting surface of the shaft, thereby minimizing trauma to the surrounding tissue when changing the orientation of the tool. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Poloyko by providing an elongated hollow outer tube over the inner tube 36 wherein the outer tube is rotatable relative to the handle assembly, inner tube 36, and distal tool as taught by Poncet in order to minimize trauma to the surrounding tissue while changing the orientation of the tool. So modified, the hollow outer tube is connected at a proximal end to the handle assembly, is rotatably secured at a distal end to the suturing

assembly, and is the hollow inner tube is located within the hollow outer tube. Rotating the handle assembly while holding the outer tube stationary concurrently rotates the hollow inner tube 36 and the suturing assembly as a unit.

The suturing assembly comprises a holding member (track containing needle therein), also considered to be a needle guide having suture aperture 48, that removably holds the needle 52, and a needle cover 38. There is a thin flexible rod 64 arranged within the hollow inner tube 36 wherein the rod is connected at a proximal end to the handle assembly and has a distal end configured for connection to a needle located within the suturing assembly. The plunger 62 attaches to the needle by means of the thin rod 64.

Regarding claims 3-5, Poloyko does not teach that the needle is hollow and has an open, sharp tipped distal end with rounded edges such that a suture may extend from an aperture on a proximal surface of the needle to an opening at the distal end of the needle. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide such a needle since such needles were notoriously old and well known to be used for suturing.

Regarding claim 7, all materials have some degree of flexibility. Alternatively, it would have been obvious to increase the flexibility of the shaft of the device in order to allow the device to access and suture more remote anatomies.

Regarding claim 9, Poloyko does not teach that there is a spring that biases the needle plunger into an extended position and the needle into a retracted position. It was well known to provide a spring on such plunger actuating mechanisms in order to

bias the plunger into an extended position and the device into an non-actuated position. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Poloyko by providing a spring that biases the needle plunger into an extended position and the needle into a retracted position in order to prevent the needle from projecting from the distal end without the surgeon intending for the needle to do so.

Regarding claims 10 and 11, Poncet teaches that the functional distal tool may be angled away from the longitudinal axis of the hollow outer tube. (Figure 1) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Poloyko by having the suture assembly be angled away from the longitudinal axis of the outer tube in order to allow the suture assembly to access a wider variety of anatomies. It would have been obvious to have said angle be a 45 degree angle since the court has held that it is within the knowledge of a person skilled in the art to determine optimal range for the function of a device.

Regarding claim 26, the device of Poloyko is substantially rigid. Poncet teaches that such devices may be bent in order to allow the tools to reach more remote anatomies. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a bend along the shaft of the modified Poloyko device in order to achieve these benefits. So modified, the hollow outer tube would have a bent portion.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Poloyko et al. (US 5,741,276) in view of Poncet et al. (US 5,254,130) and further in view of Andreas et al. (US 5,797,929).

Poloyko and Poncet teach all elements of claim 12 as previously discussed except for the hollow outer tube having a sleeve rigidly attached thereto wherein the sleeve has a diameter greater than the diameter of the hollow outer tube and the handle assembly is rotatable within the sleeve. Andreas teaches a related suturing system wherein a hollow outer tube 104 is rotatable relative to a handle assembly (includes element 140 and the proximal portion of shaft 106) and a hollow inner tube 106. Andreas teaches providing a sleeve 130 at the proximal end of the hollow outer tube 104 having a diameter greater than that of the hollow outer tube. The handle assembly rotates within the sleeve 130. It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the apparatus taught by Poloyko and Poncet by providing the outer tube with a sleeve as taught by Andreas in order to provide a user with a larger-diameter that may be gripped to more easily cause relative rotation between the inner and outer tubes. So modified, at least a portion of the the handle assembly would rotate within the sleeve.

Claims 14 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poloyko et al. (US 5,741,276) in view of Poncet et al. (US 5,254,130) as applied to claim 1 above and further in view of Djurovic (US 6,315,784).

Regarding claims 14 and 25, Poloyko and Poncet teach all elements of claim 14 as previously discussed except for a suture holder attached to the needle guide wherein the needle guide is secured between the needle cover and the suture holder. The suture material of Poloyko is fed from a supply outside the body through the flexible actuating rod and to the suturing assembly. Djurovic teaches that a suture holding spool containing a supply of suture material may be attached at the distal end of a suturing device. (Figure 1) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Poloyko by providing a suture holding spool within the suture assembly since Djurovic teaches that this was a known alternative for feeding suturing material to the needle. Since the needle cover 38 is the outer housing of the suture assembly and the needle guide is the track containing the needle therein, by positioning the suture holder within the suture assembly as taught by Djurovic, the needle guide would be secured between the suture holder and at least some portion of the needle cover.

So modified, a spool is positioned within element 38, and a suture thread is fed from the spool to the needle 52 located within the curved needle guide. For this configuration to be possible, the suture must pass through a suture hole in the needle cover 38 and into the needle guide to reach the needle 52. As can be seen in Figure 2 of Poloyko, regardless of where the suture hole is located within element 38, it will be adjacent a concave portion of the curved needle guide.

Response to Arguments

Applicant's arguments with respect to claims 1-12, 14, 25 and 26 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric Blatt/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734